

Appendix 3

**BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE**

INTERNATIONAL FORM

TO UNIVERSITY OF NEWCASTLE UPON TYNE	RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITORY AUTHORITY identified at the bottom of this page
6 Kensington Terrace Newcastle upon Tyne NE1 7RQ UK NAME AND ADDRESS OF DEPOSITOR	

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: hES - NCL1	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: P-05-001
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input type="checkbox"/> a scientific description None given <input type="checkbox"/> a proposed taxonomic designation CM 13-01-05 (Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 13-01-05 (date of the original deposit) ¹	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and Request to convert the original deposit to a deposit under the Budapest Treaty was received by it on CM 13-01-05 (date of receipt of request for conversion)	
V. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: DR. CHARLES J. HUNT Address: NIBSC, UK STEM CELL BANK, BLANCHE LANE, POTTERIES BAR, HERTS EN6 3QQ	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s): <i>C.J.H.</i> Date: 13-01-05

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

TO DR M STOJKOVIC UNIVERSITY OF NEWCASTLE UPON TYNE INSTITUTE OF HUMAN GENETICS CENTRAL PARKWAY NEWCASTLE UPON TYNE NE1 3BZ UK NAME AND ADDRESS OF DEPOSITOR	INTERNATIONAL FORM
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I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:
HESCDf-NCL	04010601

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

A scientific description
 A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,
which was received by it on 06 January 2004 (date of the original deposit)¹

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International
Depository Authority on _____ (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on _____ (date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
HPA
Porton Down
Salisbury SP4 0JG

Signature(s) of person(s) having the power
to represent the International Depository
Authority or of authorized officials(s):

Date: 14/02/05

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
DR M STOJKOVIC
UNIVERSITY OF NEWCASTLE UPON TYNE
INSTITUTE OF HUMAN GENETICS
CENTRAL PARKWAY

NEWCASTLE UPON TYNE
NE1 3BZ
UK

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY OF STATEMENT
IS ISSUED

VIABILITY STATEMENT
Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITORY AUTHORITY
identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: DR M STOJKOVIC UNIVERSITY OF NEWCASTLE UPON TYNE INSTITUTE OF HUMAN GENETICS CENTRAL PARKWAY Address: NEWCASTLE UPON TYNE NE1 3BZ UK	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 04010601 Date of the deposit or of the transfer: 06 January 2004
III. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 06 January 2004. On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> 3 viable</p> <p><input type="checkbox"/> 3 no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

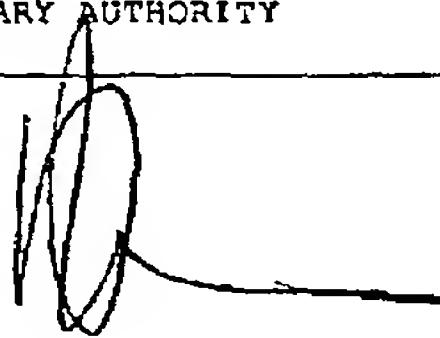
Form BP/4 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED⁴

THE PATENT DEPOSIT- hESCDf-NCL - ACCESSION NUMBER 04010601 LOT NUMBER 04/B/019 HAS A VIABLE CELL COUNT OF 5 X 10⁵ CELLS/MLS AND A VIABILITY OF 91.5%.

II. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis
ECACC HPA
Address: Porton Down
Salisbury
Wiltshire
SP4 0JG



Signature(s) of person(s) having the power
to represent the International Depository
Authority or of authorized official(s):

Date: 16/02/05

⁴ Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

THE COMPLETE CELL SOLUTION



Health Protection Agency, Porton Down and European Collection of Cell Cultures

This document certifies that
CELL LINE hESCdF-NCL
Deposit Reference 04010601

has been accepted as a patent deposit, in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on
06 January 2004

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Dr D H Lewis
General Manager
ECACC

Certificate of Analysis

Product Description hESCDP - NCL
Lot Number 04/B/019

Test Description: Cell Count, Viability and confluence of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >100% viable cells
- $>2 \times 10^6$ viable cells/ml
- Confluent within 2 days

Date: 19/05/04

Result:

Viable Cell Count:	5×10^6 cells/ml
Percentage Viability:	91.5%
Confluent within:	2 days
Overall Result:	PASS

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 30107

Date: 21/6/04

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by *H.P. Kelly, Ph.D., FRCACC*, Head of Quality. 14.7.04 Date

Certificate of Analysis

Product Description hESCD - NCL
Lot Number 04/B/019

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.
 SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. hyorhinis*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 30107

Date: 28/5/04

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Detection of mycoplasma by PCR using Mycoplasma-specific PCR Primers validated by ECACC
 SOP ECACC/073

Acceptance Criterion/Specification: Positive controls yield a single 280 bp amplification product. Negative Control yields no amplified product. The criteria for a positive test result is the yield of a single 280bp PCR product

Test Number: 30107

Date: 28/5/04

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by *M. H. J. S. P. RECACC, Head of Quality..14/7/04.. Date*

Certificate of Analysis

Product Description hESCDf - NCL
Lot Number 04/B/019

Test Description: Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01

Acceptance Criterion/Specification: All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 30107

Date: 16/5/04

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by *M.M. Patel, Ph.D.*, Head of Quality, 14/17/04 Date